

## 7 510K Summary

### **510(K) SUMMARY FOR ALSIUS CORPORATION'S ICY™ CATHETER MODEL IC-3893A**

**Submitter's Name, Address, Telephone Number, and Contact Person:**

ALSIUS CORPORATION  
15770 Laguna Canyon Road, Suite 150  
Irvine, CA 92618

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Phone: 949-453-0150  
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Email: kcollins@alsius.com

**Name of Device:**

ICY™ Catheter Model IC-3893A

**Common or Usual Name:**

Central Venous Catheter (short term) and Thermal Regulating System.

**Classification Name:**

21 CFR 870.5900 System, hypothermia, intravenous, cooling

**Predicate Device:**

K030421 Alsius Icy™ Catheter Kit Model IC-3585A

Decision Date 10/23/2003

Decision Substantially equivalent (SE)

**Indications for Use**

The Icy™ Catheter Model IC-3893A, connected to the COOLGARD™ 3000/Alsius Catheter Thermal Regulation System, is indicated for use:

- in cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and
- to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

**Technical Characteristics:**

The ICY™ catheters are multi lumen intravascular catheters in various sizes. In common across the models, the catheters have two lumens that are used to circulate sterile saline to exchange heat with the central venous blood supply. When the heat exchange feature of the catheter is in use, heated/chilled saline is pumped through the heat exchange lumen, expanding the diameter of the distal portion of the catheter to a nominal 5mm or 8mm where the heating/cooling membranes interface with the patient's circulating blood. The

inflow lumen/outflow lumen forms a closed-loop system through which the heated/chilled saline circulates. The chilled saline is not infused into the patient.

Additional lumens of the Alsius Icy™ Catheter Model IC-3893A consist of a standard guide wire lumen that can be used as a primary infusion lumen, and two additional infusion lumens within the shaft.

The Icy™ Catheter Model IC-3893A is the same as the predicate device, the Icy™ Model IC-3585A except that it has two extra infusion lumens with a corresponding increase in shaft diameter. The heat exchange capability of the two catheters is the same.

	Icy™ IC-3585A Predicate - K030421	Icy™ IC-3893A NEW
Saline Circuit	Same	
Tip Infusion Lumen	Same	
Mid shaft Infusion Lumen	x	✓
Lower shaft Infusion Lumen	x	✓
Length	35cm insertion length 38cm tip to manifold	
Shaft Diameter	8.5 Fr	9.3 Fr
Cooling Balloons	3 Balloons of the same dimensions and at the same locations down the catheter shaft from the tip	

The Catheter blood contact surfaces are coated with DuraFlo® Treatment, a heparin coating manufactured by Edwards Lifesciences Corporation.

The Alsius Catheters are supplied sterile for single-use only.

#### Principles of Operation:

The CoolGard™ 3000 system automatically adjusts the temperature of the heater/chiller saline bath to achieve the patient target temperature that has previously been set by the attending physician. This is done via data from a temperature probe in the patient that interfaces with the temperature controller. This principle of operation is identical to currently marketed devices.

#### Summary of the Basis for Finding of Substantial Equivalence:

The CoolGard and Catheter Thermal Regulation System indication statement and intended use is identical to the predicate device. Principle of operation is the same as the predicate

device. The technical characteristics and materials used are very similar to the predicate device.

**Conclusion**

In summary, descriptive information and performance data demonstrate that the Alsius Icy Catheter™ Model IC-3893A characteristics do not raise new questions of safety and effectiveness. Where appropriate, performance data demonstrate equivalence. The Icy Catheter™ Model IC-3893A is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 17 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kenneth A. Collins, MD  
Executive Vice President  
Alsius Corporation  
15770 Laguna Canyon Road, Suite 150  
Irvine, California 92618

Re: K052443  
Trade/Device Name: Alsius Icy™ Catheter Model IC-3893A  
Regulation Number: 21 CFR 870.5900  
Regulation Name: Thermal regulating system  
Regulatory Class: II  
Product Code: NCX  
Dated: September 2, 2005  
Received: September 8, 2005

Dear Dr. Collins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

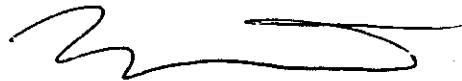
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



for Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K052443

Device Name: Alsius Icy™ Catheter Model IC-3893A

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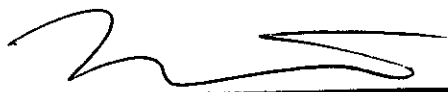
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

Page   1   of   1  

**510(k) Number**   K052443